

### REMARKS

In response to the restriction requirement of January 13, 2006, Applicants elect group I (Claims 1-19), *with traverse*. Applicants traverse because at least groups IV-V must be recombined into a single group.

The improper restriction of Groups IV and V are essentially moot in the subject case, in light of Applicants' election above and, accordingly, Applicants do not address the issues presented in detail here, reserving the right to do so in one or more divisional application. However, because of current uncertainty with respect to proposed changes in divisional practice currently under consideration by the Patent Office, the issues presented by the improper restriction of groups IV-V are addressed briefly below.

Applicants note that the proper procedures to be followed with respect to groups IV-V are found at MPEP 803.02, and relate to *election of species* rather than restriction *per se*. While the Office is free to require *election of species* (in this case, "in vitro" vs. "in vivo" embodiments) to simplify initial examination, **the Office simply has no statutory authority whatsoever to reject a claim for misjoinder of invention** (the *per se* definition of restriction as applied to a single claim, as the Examiner has here done, e.g., for claims 31-35) As the Courts have noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

*See, In Re Weber, Soder and Boksay* 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978). It has, thus, long been held that the Office simply may NOT divide a claim up into multiple fragmentary claims under the guise of restriction practice.

Furthermore, even if the restriction is somehow intended to be directed to inherent claim alternatives (the requirement does not reflect *Markush* style alternatives actually found in independent claim 31; but, rather, to *dependent* limitations in dependent claims 36 and 37), the dictates of *In re Harnish* 206 USPQ 300 (CCPA 1980) must still be applied. *Harnish* holds that claims which lack unity may be *rejected* on that basis—but *Harnish* also expressly holds that lack of unity provides no basis at all for *restriction*, i.e., that issues of unity are gleaned from judicial precedent and *not* 35 USC § 121. In *Harnish*, the Court indicated that the requirements for making a *rejection* for lack of unity include that the elements so rejected must be “repugnant to scientific coclassification.” This standard (which is unrelated to restriction practice in any event) presents a high hurdle, and can literally never be met by dependent claim elements.

Because the MPEP seems at first glance to consider restriction practice of *Markush* style claim elements with respect to Unity of Invention (MPEP 803.02), a great deal of confusion has, unfortunately, become commonplace in the Office as to appropriate restriction practice when considering questions of restriction practice for *Markush* style claim elements (even when presented in dependent claims). It is instructive to consider how this section arose in the MPEP to understand what the law is and what it is not when performing this analysis.

After the *Weber* decision, noted above, a previous version of 803.02 that purported to fashion a rejection for “misjoinder” of a *Markush*-style claim was actually *cancelled out of the MPEP*. That is, for a time, MPEP 803.02 simply stated:

the subject matter formerly under this subtitle has been cancelled in view of the decisions *In Re Weber et al.* 198 USPQ 328 (CCPA 1978) and *In Re Haas* 198 USPQ 334 (CCPA 1978).

It was plainly well understood that *Weber* and *Haas* categorically and unequivocally forbade the Office from making such “restriction rejections.” In 1980, the Courts again considered the issue of misjoinder of invention in the seminal case of *In Re Harnisch* 206USPQ2d 1059, which considered whether there was a *non-statutory* basis for a rejection for “lack of unity” *that was entirely distinct from restriction practice authorized by 35 USC § 121*. The *Harnisch* Court was plainly concerned that the two issues would be confused, noting that:

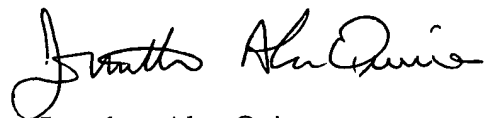
It should be clear from what we have said that we adhere to our holdings in *In re Weber*, supra and *In Re Haas (Haas II)*, supra. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be construed to have such an effect. The “unity of invention” concept is not to be confused with the “misjoinder” under 35 USC 121 rejection employed in *In re Weber*. In Weber, we dealt with the use of 35 USC 121, which deals only with restriction requirements, to support the rejection of a single claim. Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an improper Markush group.

The Court’s concern that the Patent Office would confuse the issues of divisional practice under 35 USC § 121 and non-statutory unity of invention considerations that are entirely separate from restriction practice has, unfortunately, proven to be well founded. In reinstating MPEP § 803.02, the organizers of the MPEP addressed *Harnisch* (it is the Court decision that now underlies the section), but awkwardly left the original previously cancelled headings for the section in place, seeming to suggest that the “unity of invention” issue under *Harnisch* is really one of restriction practice. As the Court plainly, expressly and repeatedly made clear (*see above*), it simply is not.

**Applicants request that the Examiner expressly rejoin groups IV and V. In the event that the Examiner does not rejoin these groups, Applicants request an Examiner Interview PRIOR to any action on the merits.**

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Respectfully submitted,



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Attachments:

- 1) A petition to extend the period of response for 4 months;
- 2) A transmittal sheet; and,
- 3) A receipt indication postcard